

### **REMARKS**

The above referenced application has been reviewed in light of the Office Action mailed July 24, 2008. Claims 1-9, 12-22, 24 and 25 are currently pending in this application with Claims 1 and 12 being in independent form. In view of the remarks to follow, allowance of this application is respectfully requested.

Claims 1-9, 12-22, 24, and 25 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action states that the originally filed application does not include “the needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than  $\frac{1}{2}$  the x-dimension “ $x_1$ ” of the enlarged transition portion.”

The specification clearly provides for the needle point being displaced a predetermined distance with respect to the longitudinal axis, the predetermined distance being less than  $\frac{1}{2}$  the x-dimension “ $x_1$ ” of the enlarged transition portion. For example, lines 18-19 on page 3 recite that the x-dimension and the z-dimension correspond to the height and width respectively of the needle end portion. As shown in FIG. 5, and described on page 7, the formed needle point is both displaced from the central axis extending through the center of the needle body and displaced from the lowest surface of the transition portion corresponding to a distance “a.” Distance “a” is determined by angle “ $\alpha$ ” which ranges between about 2° and about 10°. As the specification does, in fact, describe and show the displacement of the needle point, Applicants respectfully submit that the above rejection is improper. Thus, it is respectfully submitted that the rejection of claims 1-9, 12-22, 24, and 25 under 35 U.S.C. §112 should be withdrawn.

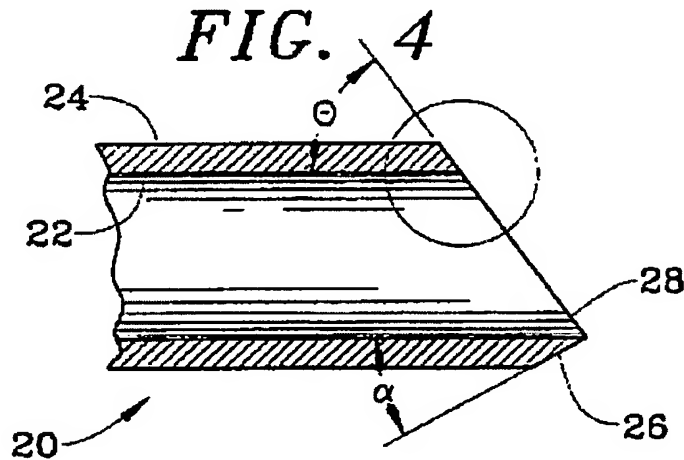
Claims 1-9, 12-22, 24 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,537,593 to Alchas in view of U.S. Patent No. 5,403,344 to Allen and U.S. Patent No. 5,733,266 to Gravlee, Jr. Applicants respectfully submit that Alchas, Allen, and Gravlee Jr., either alone or in combination, fail to teach or suggest the claimed apparatus and that there is no reason, motivation, or suggestion in Alchas, Allen, or Gravlee Jr. to combine the references.

As acknowledged by the Examiner, neither Alchas nor Allen teach a surgical needle including, *inter alia*, a “needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than  $\frac{1}{2}$  the x-dimension ‘ $x_1$ ’ of the enlarged transition portion, and at least one side of the needled end portion being displaced by an angle  $\alpha$  from a plane parallel to the longitudinal axis, the angle  $\alpha$  being between about  $2^\circ$  and about  $10^\circ$ , wherein the side of the needled end portion displaced by angle  $\alpha$  from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point,” as required by both independent Claims 1 and 12.

The Examiner relies on Gravlee Jr. to cure the deficiencies of Alchas and Allen. Specifically, in the Office Action it is asserted that Gravlee Jr. teaches “the needle point (28) being displaced a predetermined distance with respect to the longitudinal axis (Fig. 4) and wherein the predetermined distance is less than  $\frac{1}{2}$  the x-dimension ‘ $x_t$ ’ of the enlarged transition portion (Fig. 4),” and “at least one side of the needled end portion being displaced by an angle alpha from a plane parallel to the longitudinal axis (Fig. 4), the angle being between about  $2^\circ$ , and about  $10^\circ$ , wherein the side of the needled end portion displaced by angle alpha from the plane parallel to the longitudinal axis has a

substantially continuous slope between the enlarged transition portion and the needle point.”

Gravlee Jr. discloses a hypodermic needle including a hollow shaft 20 having a substantially cylindrical inner surface 22 and a substantially cylindrical outer surface 24. The needle includes a beveled surface 26 extending between and connecting the inner surface 22 and the outer surface 24 of the hollow shaft 20. As illustrated in FIG. 4, reproduced hereinbelow, the beveled surface 26 forms a cutting edge 28 at the intersection between the beveled surface 26 and the inner surface 22 of the needle.



As shown in Fig. 4, reproduced above, Gravlee Jr. fails to have an enlarged transition portion. Thus, in contrast to the Examiner’s assertions, Gravlee Jr. fails to disclose, inter alia, the side of the needled end portion having a substantially continuous slope between an enlarged transition portion and the needle point, as required by Claims 1 and 12.

Additionally, Gravlee Jr. discloses that “[t]he angle  $\alpha$  between the beveled edge 26 and the inner surface of the needle shaft is about 15° to about 60°, preferably about

40°.” (See Gravlee Jr. at Col. 3, lines 42-44). Accordingly, in contrast to the assertions in the Office Action, Gravlee Jr. also fails to disclose, inter alia, “the angle  $\alpha$  being between about 2° and about 10°,” as required by Claims 1 and 12. In fact, the smallest angle disclosed in Gravlee Jr. (i.e., 15°) is **50% greater** than the largest angle that is claimed in Claims 1 and 12 (i.e., 10°). Thus, Gravlee Jr. does not disclose or even remotely suggest “the angle  $\alpha$  being between about 2° and about 10°.”

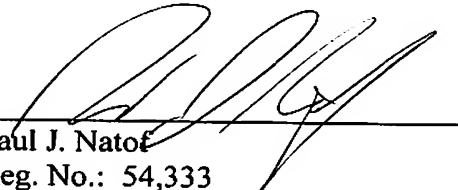
Further, the combination of a non-coring needle assembly (Alchas), a hypodermic needle (Gravlee Jr.), and a surgical needle (Allen) is improper. Alchas is directed to a hollow cannula for transferring liquid to and from a container having a penetrable stopper that prevents coring of the stopper by providing a flat portion on the closed distal end of the cannula which acts as a non-coring stopper piercing point. Gravlee Jr., on the other hand, discloses a hypodermic needle having a cutting edge between the beveled surface and the inner surface of the needle. The cutting edge may include a trailing portion which is rounded to allow the tissue to be punctured by the leading cutting edge while preventing a plug of tissue from being cut out by the trailing cutting edge of the needle. Contrary to the Examiner’s proposed combination, one of ordinary skill in the art would not combine the geometries of a needle having a closed distal end with a needle having an open distal end. Further, one of ordinary skill in the art would not look to combine two liquid transferring needles that teach solutions to the problem of plug formation in two completely different ways to solve a completely different problem related to suture needles.

Accordingly, in view of the foregoing remarks/arguments, Applicants respectfully submit that the rejections of Claims 1 and 12, as being unpatentable under 35 U.S.C. §103(a) over Alchas in view of Allen and Gravlee Jr. has been overcome.

Since Claims 2-9, which depend from Claim 1, and Claims 13-22, 24, and 25, which depend from Claim 12, contain all of the limitations of Claims 1 and 12, respectively, for at least the reasons presented above regarding the patentability of Claims 1 and 12, Applicants respectfully submit that each of Claims 2-9, 13-22, 24, and 25 is also patentable over Alchas in view of Allen and Gravlee Jr.

In view of the foregoing remarks, Applicants submit that all of the claims are in proper format and are patentably distinct from the references of record and are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

Respectfully submitted,

  
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